U.S.S.N. 10/691/928

FILED: OCTOBER 23, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

The Claims

- 1. (previously presented) A topical antifungal composition comprising:
- a) a therapeutically effective amount of an antifungal compound for treating a fungal disease or a pharmaceutically acceptable salt thereof; and
- b) a therapeutically effective amount of a low to low-medium potency steroidal antiinflammatory causing minimal skin atrophy, striae and hypopigmentation, in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone.
- 2. (previously presented) The antifungal composition of claim I wherein the steroidal antiinflammatory has the following structure:

wherein R₁, R₂, R₃, and R₄ taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, and phenyl groups; R₁ and R₂ taken together can be C3-C10 cycloalkyl; and R₃ and R₄ taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, phenyl, C7-C10 phenylalkyl, carboxylate, sulfonyl, phosphoryl, and phosphonyl groups.

45074413v1

FILED: OCTOBER 23, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

- 3. (previously presented) The composition of claim 1 wherein R₁, R₂, R₃, and R₄ groups are independently H, CH₃, ethyl, propyl, phenyl, and phenylmethyl groups.
- 4. (previously presented) The composition of claim 2 wherein the steroidal antiinflammatory is desonide and the antifungal compound is clotrimazole.
- 5. (original) The composition of claim 4 containing 0.01 wt % to 5.0% wt % describe.
- 6. (original) The composition of claim 5 containing 0.1 wt % to 5 wt % clotrimazole.
- 7. (previously presented) The composition of claim 1 wherein the steroidal antiinflammatory is selected from the group consisting of Fluorinolone acctonide, Hydrocortisone
 valerate, Hydrocortisone butyrate, Alclametasone dipropionate, Desonide, and hy drocortisone
 probutate.
- 8. (original) The composition of claim 1 wherein the antifungal is selected from the group consisting of polyene type antifungal agents and azole type antifungal agents.
- 9. (original) The composition of claim 8 wherein the antifungal is selected from the group consisting of Amphoterican B, Nystatin, Flucytosin, Natamycin, Ketoconazole, Econoazole, Miconazole, Itraconazole, Fluconazole, Econazole, Clotrimazole, Griseofulvin, Oxiconazole, Terconazole, Tioconazole, Clotrimazole, Silver Sulfadiazine, Ciclopirox olamine, and Terbinafine.
- 10. (original) The composition of claim 1, wherein the composition is formulated as a cream, ointment, gel, lotion, foam, powder, acrosol, spray, shampoo, or liquid solution.

092687/00002

U.S.S.N. 10/691,928

FILED: OCTOBER 23, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

- further comprising: at least one solvent, at least one emollient, at least one humectant, at least one preservative, and at least one emulsifier; and optionally including an acid, base, or buffering agent to adjust the pH.
- 12. (original) The composition of claim 11, wherein the solvent is selected from the group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycols, polypropylene glycols, and polyurethane compounds; the emollient is selected from the group consisting of white petrolatum, mineral oil, propylene glycol dicaprylate, lower fatty acid esters and lower alkyl ethers of propylene glycol, cetyl alcohol, ectostearyl alcohol, stearyl alcohol, stearic acid, cetyl esters wax, spermaceti wax, and white wax; the humectant is selected from the group consisting of glycerin and sorbitol; and the emulsifier is selected from the group consisting of glyceryl monostearate, glyceryl monoleate, stearic acid, polyoxyethylene cetyl ether, polyoxyethylene stearyl ether, and polyethylene glycol stearate; wherein the optional acid is selected from the group consisting of hydrochloric acid and phosphoric acid, the optional base is chosen from diethanolamine, triethanolamine, and sodium hydroxide, the optional buffering agent is chosen from monobasic sodium phosphate and dibasic sodium phosphate, and the preservative is chosen from benzyl alcohol, sodium benzoate and parabens.
- 13. (original) The composition of claim I wherein the antifungal is in an amount effective to treat fungal disease selected from the group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.

U.S.S.N. 10/691,928

FILED: OCTOBER 23, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

14. (previously presented) A method of treating a fungal disease comprising administering to a subject in need of treatment the composition of any of claim 1-13 or 17, with a thin application of the composition two times per day to the affected areas.

15. (original) The method of claim 14 wherein the subject is a child of under 10 years old.

16. (original) The method of claim 14 wherein the fungal disease is selected from the group consisting of timea pedis, timea capitis, timea corporis, timea versicolor, scalp disorders, timea cruris, and candidiasis.

17. (previously presented) The composition of claim 1 wherein the steroidal antiinflammatory is not halogenated.